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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,220	02/12/2002	Tadashi Kumamoto	UTSD:771US	6187

7590 08/25/2004

FULBRIGHT & JAWORSKI L.L.P.
A REGISTERED LIMITED LIABILITY PARTNERSHIP
SUITE 2400
600 CONGRESS AVENUE
AUSTIN, TX 78701

EXAMINER

SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/074,220	Applicant(s) KUMAMOTO ET AL.	
	Examiner Sally A Sakelaris	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-143 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-143 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-17 are drawn to methods for predicting irritant potential of a candidate substance through measuring nucleotide release in response to an inflammatory agent, classified in Class 435, subclass 4.

II. Claims 18-40 are drawn to methods for preventing or treating an inflammatory response through administration of a NTPDase, classified in Class 514, subclass 12.

III. Claims 41-72 are drawn to a method of screening for modulators of inflammation by determining the expression of a NTPDase as classified in for example, Class 435 subclass 4, 6, 7.1.

IV. Claims 73-143 are drawn to a method of treating a hyperactive immune response through administration of a NTPDase inhibitor or a P2-receptor inhibitor, classified in for example, Class 514, subclass 12 or 44.

2. Inventions I-IV are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different method inventions require different steps to accommodate the involvement of different biomolecules, necessary reagents, buffers, and apparatus. The method of group I involves the steps necessary to predict irritant potential of a candidate substance. Group II requires preventing an inflammatory response through administration of an NTPDase. Group III requires steps involved in a method of screening for modulators of inflammation

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wherein the expression of a NTPDase is measured. Lastly, Group IV requires the steps involved in a method of treating a hyperactive immune response through administering a NTPDase inhibitor or a P2-receptor inhibitor. In the instant case, the different inventions are drawn to methods comprising mutually exclusive subgenuses of components and further comprising different method steps.

3. This application contains claims directed to many patentably distinct species of the claimed invention:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from the following list for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

4. Regardless of whichever Group Applicant elects, Applicant is further required under 35 U.S.C. 121 to elect:

A) a **single specific** method of measuring nucleotide concentration if Group I is elected. For example, either claims related to an enzymatic assay will be elected(claims 11 and 12) or claims related to thin layer chromatography will be elected(claim 13).

B) a **single specific** NTPDase to be administered if Group II is elected. For example, a **single** NTPDase from claims 19, 20, 33, 34, will be elected.

C) a **single specific** means of screening for modulators for a **single specific** type of NTPDase expression if Group III is elected. For example one means will be elected for determining the expression; from either an immunoassay of claims 47-49, mRNA levels of claims 50-53 and further that a **single** NTPDase from claim 48 will be elected.

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D) a **single specific** NTPDase inhibitor **or** P2-receptor inhibitor for treating a hyperactive immune response if Group IV is elected. Applicant will need to elect a single composition for administration; a specific NTPDase inhibitor(one of claims 74-76, 80, 88, 89, 101 etc), and further one specific type of the sub-group that they elect. For example if applicant picks an anti-NTPDase antibody as their inhibitor then they must further elect one antibody from claim 78. The same is true if applicant were to elect an antagonist(from claims 76-77), an antisense oligonucleotide(79, 91 etc), a chemical substance or a P2-receptor inhibitor.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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The different NTPDases, NTPDase inhibitors, P2-receptor inhibitors have significantly different chemical structures and function through different mechanisms. The different methods of using these different biomolecules and compositions who are themselves each different make these species independent and patentable over one another.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris

8/19/2004



GARY BENZION
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600